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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/825,964
Filing Date: April 15, 2004
Appellant(s): HERUTH ET AL.

_____
Jason D. Kelly
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 30, 2009 appealing from the Office action

mailed March 23, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to
the examiner which may be related to, directly affect or be directly affected by or have a bearing
on the Board's decision in the pending appeal:

Notice of Appeal for U.S. Patent Application Serial Number: 11/081786

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in
the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2005/0042589	Hatlestad et al.	2-2005
7,207,947	Koh et al.	4-2007

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

2.   Claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73 are rejected under 35

U.S.C. 103(a) as being unpatentable over Hatlestad et al. (U.S. Patent Application Publication

Number 2005/0042589 A1) in view of Koh et al. (U.S Patent Number 7,207,947).

In regard to claims 20-23, 26-33, 35-38, 40, 43-45, 53, 55, 57-62, 72 and 73, Hatlestad et al.

disclose a sleep quality data collection and evaluation device which assess sleep quality based on

detected physiological or non-physiological patient conditions. The medical device disclosed by

Hatlestad et al. comprises a plurality of sensors which generate a signal as a function of at least

one physiological parameter of a patient (paragraphs [0066]-[0070]). The device also includes

an implantable device and a microprocessor with memory. The microprocessor monitors a

plurality of physiological parameters of the patient based on the signals output by the sensors

(paragraphs [0066]-[0082]). The Hatlestad et al. device determines a value of a sleep metric that

indicates a probability of the patient being asleep based on the physiological parameters.

Hatlestad et al. disclose using the device to monitor respiratory rates and blood oxygen saturation

levels of a patient (paragraphs [0062]-[0081]). The microprocessor disclosed by Hatlestad et al.

determines variability and a mean value of at least one of the physiological parameters and

determines sleep metric values from the information gathered (paragraphs [0135]-[0162]). The

system then determines a value of an overall sleep metric based the values of the plurality of

sleep metrics and determines the value of the overall sleep metric by averaging the values of the

plurality of sleep metrics (paragraphs [0090]-[0103]). Hatlestad et al. further disclose the device

including a memory used to store threshold values, wherein the processor compares the value of

the sleep metrics to the threshold values and determines whether the patient is asleep based on

the comparison (paragraphs [0080]-[0103]). Hatlestad et al. disclose a means for monitoring a

plurality of physiological parameters of a patient and a means for determining a value of a sleep

metric indicates based on the physiological parameters. The Hatlestad et al. device further

includes a means for generating at least one signal as a function of the physiological parameters,

wherein the means for monitoring comprises means for monitoring the physiological parameters

based on the signal. The means for determining a sleep metric expressed by Hatlestad et al.

comprises means for determining a value for each of a plurality of sleep metrics, each of the

plurality of values determined based on a respective one of the physiological parameters

(paragraphs [0135]-[0162]). The device determines a value of a sleep metric by determining a

value of an overall sleep metric based the values of the plurality of sleep metrics and a

comparison of the value of the sleep metric to a threshold value. Additionally, Hatlestad et al.

disclose a means for delivering a therapy to the patient and means for controlling delivery of a

therapy to the patient by the therapy delivery means based on the determination of whether the

patient is asleep. The Hatlestad et al. device has a storage mechanism for storing values to

access at a later time. Hatlestad et al. suggest the implantable medical device may be an

implantable neurostimulator (paragraph [0059]). In regard to the claims, Hatlestad et al. disclose

the features of the Applicant's invention as described above. Although Hatlestad et al. disclose

the use of the sensors and processor to determine a sleep state including arousal of the patient,

the Hatlestad et al. reference does not specifically disclose how the sleep metric values indicate a

non-binary probability of the sleep state of the patient. Koh et al. disclose a system and method

for detecting circadian states using an implantable medical device. The system disclosed by Koh

et al. includes determining several blood carbon dioxide and other parameters to detect circadian

states of a patient including pCO_2 levels per breathing cycle, end tidal CO_2, minute ventilation

and activity levels. Koh et al. specifically disclose gaining information regarding the detected

parameters to indicate the stage of sleep of the patient being researched (col. 13, lines 19-39, col.

13, lines 63-67; col. 14, lines 1-15). Koh et al. describe calculating a ratio of the minute

ventilation to pCO2 of a patient to determine the stage of sleep the patient is currently in during

the investigation since blood CO2 levels vary according to the stage of sleep of the patient (col.

13, lines 19-39). Other parameters are used to determine the stage of sleep of the patient

including activity data, end tidal pH level and minute ventilation. Koh et al. disclose gaining a

metric through a mathematical analysis which combines the data to determine the sleep stage of

the patient (col. 13, lines 40-67; col. 14, lines 1-15). It would have been obvious to one having

ordinary skill in the art at the time the Applicants' invention was made to modify a sleep quality

data collection and evaluation device which assess sleep quality based on detected physiological

or non-physiological patient conditions, similar to that disclosed by Hatlestad et al., to include a

device which delivers a sleep metric value which indicates a non-binary probability of the sleep

state of the patient, similar to that disclosed by Koh et al., to provide a method which includes

several parameters to assist with determining the sleep state of a patient.

(10) Response to Argument

1.   Applicant argues the prior art references fail to disclose a non-binary probability of sleep

in a subject. Examiner respectfully disagrees. As described above, the combined references of

Hatlestad et al. and Koh et al. disclose a sleep quality data collection and evaluation device

which assesses sleep quality based on detected physiological or non-physiological patient

conditions. The Koh et al. reference specifically discloses a system which detects circadian

states of a patient including pCO_2 levels per breathing cycle, end tidal CO_2, minute ventilation

and activity levels. Koh et al. disclose gaining information regarding the detected parameters to

indicate the stage of sleep of the patient being researched (col. 13, lines 19-39, col. 13, lines 63-

67; col. 14, lines 1-15). Koh et al. describe calculating a ratio of the minute ventilation to pCO2

of a patient to determine the stage of sleep the patient is currently in during the investigation

since blood CO2 levels vary according to the stage of sleep of the patient (col. 13, lines 19-39).

The Koh et al. reference further discloses various non-binary quantities which assist with

determining the stage of sleep of the patient. Koh et al. describe a patient being in stage 3/4 of

sleep in the event that their calculated ratio falls within a range of 0.75 to 1.0. Additionally, Koh

et al. describe a patient being in REM sleep if the calculated ratio is found to be less that 0.50.

Examiner submits the mathematical combination of the detected values result in a non-binary

probability of the patient being asleep based on the respective physiological parameters as

described by the Applicant. Applicant's arguments with respect to the claims are not persuasive.

2.   Applicant argues the prior art references fail to disclose a plurality of sleep quality metrics that each indicate a non-binary probability of the patient being asleep based on a respective physiological parameter. Examiner respectfully disagrees. As described above, the combined references of Hatlestad et al. and Koh et al. disclose a sleep quality data collection and evaluation device which assesses sleep quality based on detected physiological or non-physiological patient conditions. The Koh et al. reference specifically discloses a system which detects minute ventilation, activity, $etCO2$ and $\Delta_{cycle}CO2$ levels to indicate the stage of sleep of the patient being researched (col. 13, lines 1-39, col. 13, lines 63-67; col. 14, lines 1-15). Koh et al. disclose the detection of these parameters provide an indication of the state of sleep of the patient. As stated by Koh et al., the detected parameters have a certain trends during an awake state versus a sleep state of a patient (col. 11, lines 12-29). Koh et al. further state considering trend data of a patient to better assess the sleep state of the patient and comparing the trend data with threshold values to determine the stage of sleep of the patient. Applicant's arguments with respect to the claims are not persuasive.

3.   Applicant argues the prior art references fail to disclose mathematically combining a plurality of sleep metric values that each indicate a non-binary probability of the patient being asleep to determine an overall sleep metric value that indicates an overall non-binary probability of the patient being asleep. Examiner respectfully disagrees. As described above, the combined references of Hatlestad et al. and Koh et al. disclose a sleep quality data collection and evaluation device which assesses sleep quality based on detected physiological or non-physiological patient conditions. The Koh et al. reference specifically discloses a system which detects circadian states of a patient including pCO_2 levels per breathing cycle, end tidal CO_2, minute ventilation

and activity levels. Koh et al. disclose the detection of these parameters provide a metric or an

indication of the state of sleep of the patient. Koh et al. describe combining the detected metrics

and calculating a ratio to determine the stage of sleep the patient is currently in during the

investigation (col. 13, lines 19-39). The combination of the detected parameters results in an

overall non-binary probability metric which indicates an overall probability of the sleep stage of

the patient. Applicant's arguments with respect to the claims are not persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related

Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Fangemonique Smith/

Conferees:

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

/Boyer D. Ashley/

Supervisory Patent Examiner, Art Unit 3724